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Round Lake, Illinois 60073-0490
847.546.6311

Baxter

Dockets Management
Branch (HFA09305)
Food and Drug Administration
5630 Fishers Lane, Room1061
Rockville, MD 20852

Re: Federal Register Notice; August 3, 1999
Docket No. 99D-2013, CBER 9741
Draft Guidance for Industry
"Cooperative Manufacturing Arrangements for Licensed Biologics"

Dear Sir or Madam:

Baxter Healthcare Corporation, Fenwal Division, is submitting this correspondence in order to comment on the draft Guidance for Industry; "Cooperative Manufacturing Arrangements for Licensed Biologics," August, 1999.

We have noted that the Guidance document facilitates product development for biologics and provides great flexibility in situations where a single company cannot perform all manufacturing steps. The manufacturing arrangements depicted in the guidance reflect the biologic industry's need for multiple manufacturer's involvement in the production of a single biologic, few number of sites capable of manufacturing biotech products, and the need for efficient and cost-effective processes.

However, alternate means of introducing innovative technology for blood and blood component testing and treatment through cooperative manufacturing arrangements should be incorporated in this guidance document as well.

We would like suggest that the guidance be modified to address the future needs of the many blood centers faced with innovative and highly technical methods for inactivation of pathogens and pathogen testing. We would like to propose that Contract Manufacturing be expanded to allow use of blanket supplements and approvals which allow "associated or cooperative" licensed centers to contract for centralized, standardized licensable technologies such as component processing (e.g. viral and pathogen inactivation) or testing (e.g. nucleic acid testing). These technologies will have a significant impact on blood center operations and are likely to create fiscal constraints similar to those faced by biotech manufacturers as they attempt to achieve cost-effective and efficient processes.

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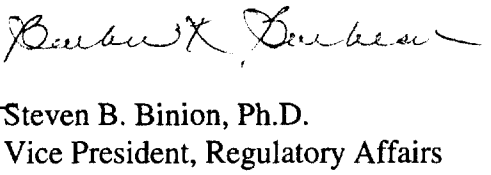
We hope that the FDA will consider these comments. We anticipate that licensed manufacturers of blood and blood components will need regulatory flexibility similar to that used by manufacturers of biotech products to efficiently and cost-effectively implement emerging technologies for pathogen controls.

We appreciate the opportunity to comment on this draft guideline. If you have any questions regarding our comments, please contact me at (847)270-4294, [FAX (847)270 2506].

Sincerely,



Steven B. Binion, Ph.D.
Vice President, Regulatory Affairs
Fenwal Division

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